

## REMARKS

### Status of the Claims

Claim 95 is presented for examination. Claims 95 stands rejected. Claim 95 is currently amended without prejudice or disclaimer. Claims 1-94 are cancelled previously without prejudice or disclaimer. No new matter is added. Reconsideration is respectfully requested.

### Amendments to the claims

Claim 95 is amended herein to overcome rejections under 35 USC §112. The amendments are supported by the specification. In particular, Examples 29 and 30 provide support for the amendments to the claim presented herein. No new matter has been introduced by way of these amendments.

### Claim rejection under 35 USC §112

Claim 95 stands rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that claim 95 recites "susceptibility of the human to development of estrogen hormone responsive cancer" but then recites "steroid hormone responsive cancer cell" and "inhibition-reversing amount of the steroid hormone." In view of this, the Examiner states, it is unclear if the scope of the cancer cells includes all steroid hormone responsive cancer cells, including those which are progesterone, testosterone and androgen responsive. Further, the Examiner states that since claim 95 recites secreted dimeric/polymeric IgA, polymeric IgM and IgG1, it is unclear if the claim is referring to the species of immunoglobulins in the alternative or in a collective group.

Applicants submit amended claim 95. Claim 95 has been amended and no longer recites "steroid hormone responsive cancer" and is now consistent in its recitation of recites "estrogen hormone responsive cancer". Hence, it is clear that the invention is directed to estrogen responsive cancers. Further claim 95 as amended recites "a level of at least one secreted immunoglobulin, selected from the group consisting of dimeric/polymeric IgA,

polymeric IgM<sub>1</sub> and IgG1". Thus amended claim 95 clearly refers to the species of the immunoglobulins in the alternative.

In view of the amendments presented, Applicants respectfully request that the rejection of claim 95 under 35 USC §112, second paragraph be withdrawn.

Claim 95 is rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the instant method claim requires the secreted dimeric/polymeric IgA, polymeric IgM and IgG1 is active in inhibiting proliferation of a steroid hormone responsive cancer cell maintained in a suitable nutrient medium under cell growth promoting conditions, and in the absence of an inhibition-reversing amount of steroid hormone. The Examiner also states that growing the steroid hormone responsive cancer in vitro under growth promoting conditions necessitates addition of steroid hormone in some range of concentration. Further, the Examiner states that the specification does not provide any objective evidence that the growth stimulating levels of steroid hormones can be separated from inhibition-reversing amount of the steroid hormone even at low levels. Hence, the Examiner points out, one of skill in the art would be forced into undue experimentation in order to define levels of steroid hormones that support growth but do not reverse the inhibition of secreted IgA, IgM, or IgG1.

Applicants submit amended claim 95. Amended claim 95 discloses a method of predicting susceptibility of an individual to development of an estrogen hormone responsive cancer based on quantitating the levels of poly Immunoglobulins in a secreted body fluid obtained. A decrease in the levels of any one of the secreted poly immunoglobulin, IgA, IgM or IgG1, as compared to normal wild type levels would indicate an increased risk of developing estrogen responsive cancer of mucosal epithelial origin. The specification provides adequate support for the amendments. Specifically, Examples 29 and 30, of the specification, describes determination of levels of IgA/IgM in plasma or body secretion of individuals to predict susceptibility of developing breast cancer.

In view of the amendments presented supra, Applicants respectfully submit that the specification describes how to make and use the claimed invention and the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation. Accordingly, Applicants respectfully request that the rejection of claim 95 under 35 USC §112, first paragraph be withdrawn.

This is intended to be a complete response to the office action mailed August 20, 2007. As a result of the foregoing, it is asserted by Applicants that the pending claim 95 is in condition for allowance and respectfully request early allowance of such claims. If any issues remain outstanding, the Examiner is respectfully requested to contact the undersigned attorney of record for immediate resolution.

## CONCLUSION

Applicant respectfully submit that the claim as amended is allowable and respectfully requests such action. The Examiner is requested to contact the undersigned attorney if such contact would be helpful in furthering the prosecution of the case.

Respectfully submitted,

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